TENNESSEE GENERAL ASSEMBLY
FISCAL REVIEW COMMITTEE

FISCAL NOTE

HB 143 - SB 811

March 3, 2015

SUMMARY OF BILL: Creates the "Tennessee Right to Try Act" for the purpose of authorizing an eligible patient to utilize an investigational drug, biological product or device that has completed phase 1 of a clinical trial but has not yet been approved for general use by the federal food and drug administration (FDA) and remains under investigation in a clinical trial that is approved by the FDA. Defines an eligible patient as an individual who has an advanced illness, has considered all other FDA-approved treatment options, has received a recommendation from the patient's physician for an investigational drug, biological product, or device, has given written, informed consent for the use of an investigational drug, biological product, or device, and has documentation from such physician that the patient meets all the aforementioned requirements.

The eligible patient's health plan or third-party administrator and provider are not obligated to pay for any care or treatments consequent to the use of an investigational drug, biological product, or device, unless required to do so by law or contract. No government agency is required to pay for any care or treatment for a patient associated with the use of any investigational drug, biological product, or device. All expenses related to such investigational treatment will be borne by the patient.

The manufacturer of an investigational drug, biological product, or device is authorized to make any such drug, product or device available to an eligible patient with or without compensation. Prohibits any entity responsible for Medicare certification, or any licensing board or disciplinary committee from revoking, failing to renew, suspending, or taking any action against a healthcare provider's certification or license based solely on the provider's recommendation to an eligible patient regarding access to treatment with an investigational drug, biological product, or device.

A manufacturer shall not be liable for any harm done to the eligible patient resulting from the use an investigational drug, biological product, or device, if the manufacturer or other person or entity is complying in good faith.

ESTIMATED FISCAL IMPACT:

NOT SIGNIFICANT

Assumptions:

- This legislation exempts any health care plan from covering any costs associated with an eligible patient's use of an investigational drug, biological product, or device.
- The use of any investigational drug, biological product, or device is not considered medically necessary; therefore, all costs associated with treatment by any such drug, product, or device will be borne by the eligible patient.
- The provisions of the bill will not affect any state sponsored health plans including the state employee, local government, and local education plans, TennCare, or the Cover Tennessee plans.
- Any necessary rulemaking provided by the Board of Medical Examiners can be accommodated during regularly scheduled Board meetings.
- Pursuant to Tenn. Code Ann. § 4-29-121, all health related boards are required to be self-supporting over any two year period.
- The Board of Medical Examiners had an annual surplus of $288,380 in FY12-13, an annual deficit of $75,431 in FY13-14, and a cumulative reserve balance of $2,365,965 on June 30, 2014.

IMPACT TO COMMERCE:

Other Fiscal Impact - Any domiciled drug, product, or device manufacturer which provides an investigational drug, biological product, or device to an eligible patient may charge a fee to cover the expenditures incurred for covering the cost of production. The increase to revenue and expenditures is indeterminable.

Assumptions:

- This legislation exempts any health care plan from covering any costs associated with an eligible patient's use of an investigational drug, biological product, or device.
- To the extent that a domiciled drug, product or device manufacturer makes available any investigational drug, biological product, or device to an eligible patient is unknown. Any such manufacturer would be authorized to charge an eligible patient a fee for access to any such drug, product, or device, likely resulting in an increase in business revenue for such manufacturer.
- The fee charged will at least cover the cost of providing the drug, product, or device to the eligible patient.
- Due to numerous unknown factors, including, but not limited to: the amount of investigational drugs, biological products or devices that will be made available by manufacturers; the number of eligible patients who will seek such drugs, products, or devices; the number of physicians willing to authorize a patient's use of such drugs, products, and devices; the price charged by the manufacturer for the use of any such drug, product or device; and the cost incurred by the manufacturer to provide such product, any fiscal impact to domiciled drug manufacturers is indeterminable.

CERTIFICATION:

The information contained herein is true and correct to the best of my knowledge.

Jeffrey L. Spalding, Executive Director

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